# eConsent: What It Is, What It Isn't, and Tools to Implement

## 10 December 2024

From 16:00 to 17:00 CET

# Agenda & Speakers

1. Why the European Forum GCP eConsent Initiative?
2. Diving into the EFGCP eConsent Suite of Tools
   - A. eConsent Terminologies – The Foundation
   - B. eConsent Study Documents Recommendations
   - C. Insights in Ethics Committees, Sponsors and Vendors Expectations
   - D. eConsent Fit-for-Purpose Study Framework
3. The Path To eConsent Success is in Your Hands
4. Questions & Answers

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# Why the European Forum GCP eConsent Initiative?

# The Informed Consent – A Fundamental Clinical Trial Process

A **process** between a **participant*** and **investigator** by which **a participant* voluntary confirms** their **willingness to participate** in a trial after having been **informed** and been provided with the opportunity **to discuss all aspects of the trial** that are **relevant to the participant's decision to participate**

*or their legally accepted representative

(ICH GCP E6 (R3)

**Without Consent – No Participants – No Clinical Trials**

# The Electronic Informed Consent (eConsent) - Not a New Concept

***Some Data of My Own eConsent Journey***

- 2013: Launched **J&J First Global Phase III eConsent Study***
- 2015-2017: Initiated and released **Transcelerate eConsent Implementation Guideline** **
- 2016: Supported **FDA eConsent Guidance**
- 2018: Supported **MHRA/HRA eConsent Position Paper**
- 2022: Supported **EMA Recommendation Paper on Decentralized Elements**

*eConsent Study Provides Insight to Shape Industry Adoption, Applied Clinical Trials 2016, Author Hilde Vanaken.
**Awareness and collaboration across stakeholder groups important for eConsent achieving value-driven adoption, TIRS 2019, Authors Hilde Vanaken et al.

# eConsent – Some Feedback of Participants & Sites

***Some Stakeholder Feedback of My Own eConsent Journey***

**+ 80% of participants** found the **video** and **quiz** to help their **understanding**

**73% of participants** felt eConsent help **understanding** better the clinical trial

**77% of sites** reported that eConsent **improved** the **consenting process**

**Sites felt** eConsent **improved data quality** and allowed a more **tailored discussion** with participants

***2013**: Results of **J&J phase III study** with **76 participants of 13 sites** being offered and using eConsent**

***2016:** Results of **Transcelerate** Participant eConsent **survey** including **3045 participants** and **Site Advisory Group** virtual **sessions** with **8 sites*****

*eConsent Study Provides Insight to Shape Industry Adoption, Applied Clinical Trials 2016, Author Hilde Vanaken.

**Awareness and collaboration across stakeholder groups important for eConsent achieving value-driven adoption, TIRS 2019, Authors Hilde Vanaken et al.

# eConsent - Where Are We Today?

**eConsent adoption is limited**

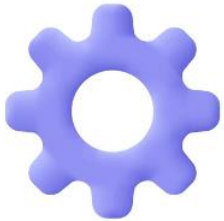
WHY?

# eConsent – What Is Hampering eConsent Implementation?

Many Different Interpretations

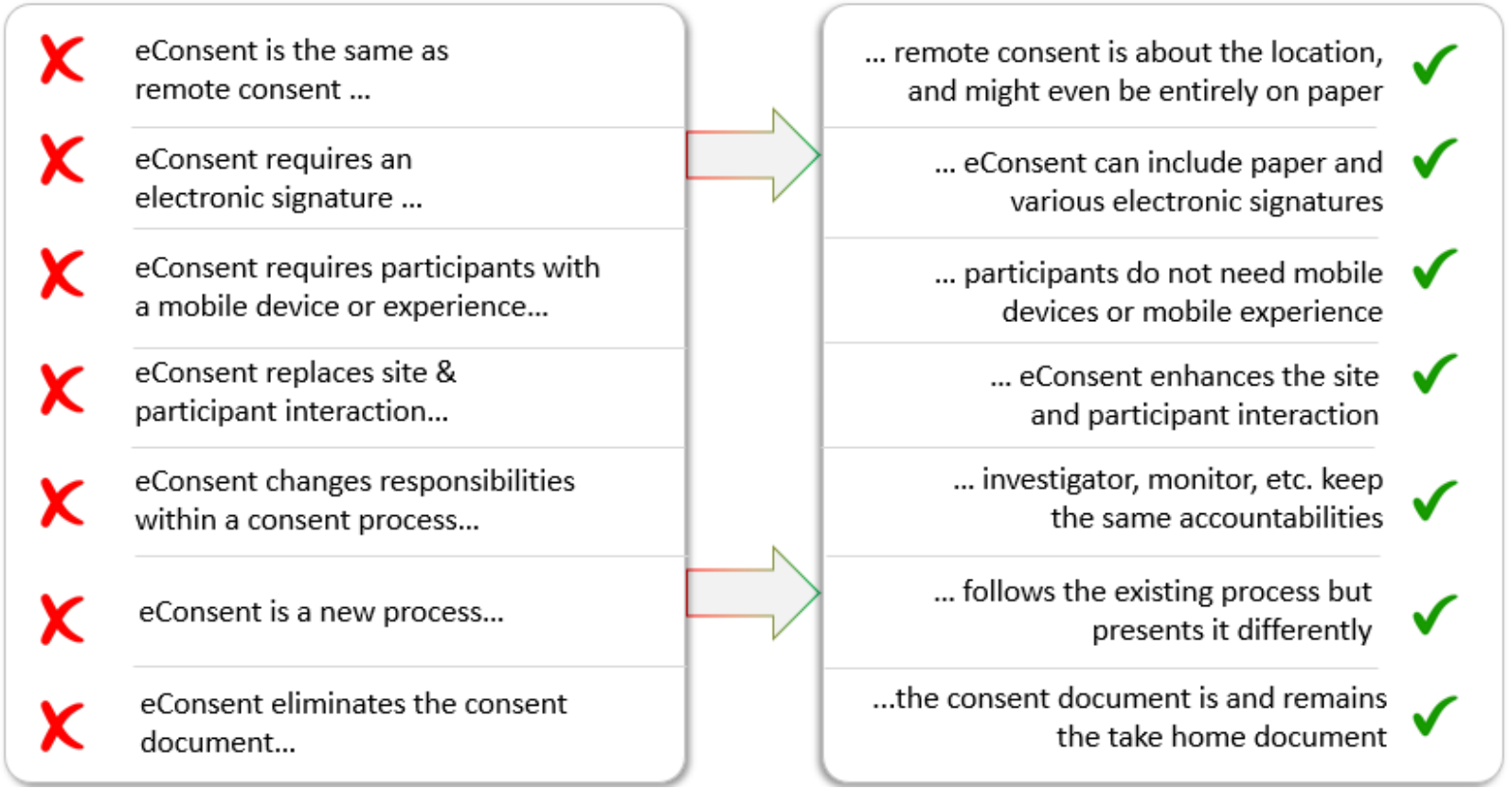
Many Disconnects

Many Unclear Processes



Limited Stakeholders Value Insights

# eConsent – Examples of Common Misunderstandings



# eConsent – Examples of Common Disconnects

## eConsent and eSignature Isn't Allowed in European Country X

eConsent and eSignatures are allowed in all European Countries and many other countries and regions such as e.g. US

| Please see relevant footnotes for responses marked with an asterisk. A footnote may be raised even though no response is given. | AT | BE | BG | CY | CZ | DE BfArM | DE PEI | DK | EE | EL | ES | FI | FR | HR | HU | IE | IS | IT | LI | LT | LU | LV | MT | NL | NO | PL | PT | RO | SE | SI | SK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Q12: Is it possible to use electronic signatures instead of wet ink? If yes, please specify in the footnotes which eIDAS category is expected for the electronic signature. | Yes * | Yes * | | | Yes * | Yes * | | Yes * | Yes * | * | Yes * | Yes * | Yes * | Yes * | Yes * | Yes | | Yes * | | Yes * | | | Yes | Yes * | Yes * | * | | Yes * | Yes * | * | Yes * |

*EMA Recommendation Paper on Decentralized Elements in Clinical Trials, 13 December 2022*

## Focusing on eSignature Only & Claiming Increased Understanding

Misaligned benefits and digital features, the method of signing does not have any impact on participant understanding

**Bringing Clarity in eConsent!**

European Forum for Good Clinical Practices (EFGCP)

# eConsent Initiative

# European Forum GCP eConsent Initiative - Mission

Non-Profit Multi-Stakeholder Initiative

to HARMONIZE **eConsent Terminologies** and **Study Documents Needs**

to INCREASE INSIGHT in **Stakeholder's Value Models** and **Country Needs**

to PROVIDE a **Fit-for-Purpose eConsent Study Framework**

Initiative launched in September 2022

**+50 Organizations - 6 Workstreams – Global Initiative**

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# Diving into the EFGCP eConsent Suite of Tools

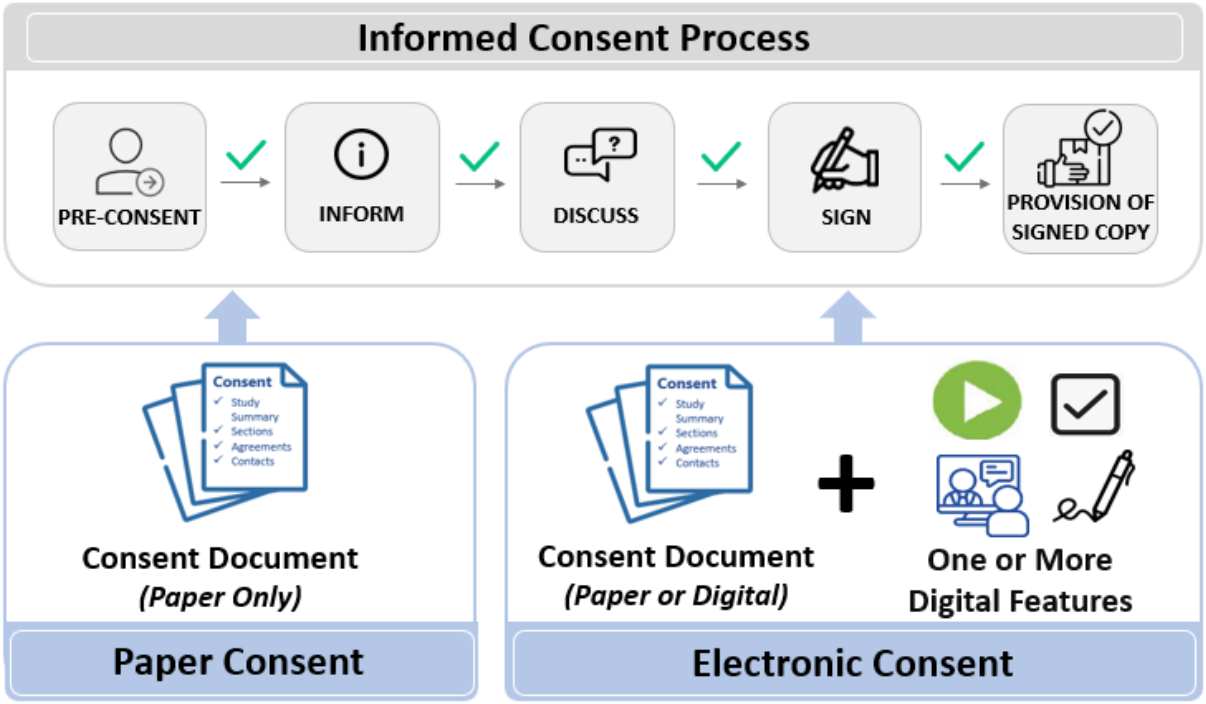
2A

# eConsent Terminologies – The Foundation!

**Library Workstream**

*Presenter: Rebecca Zeising, PharmaTrail*

# What is eConsent?




eConsent = Traditional Consent Process **Supported** by One or More Digital Features

**eConsent is an Umbrella Term**

# The Glossary of eConsent Terms and Corresponding Article

## Goal: Harmonization of eConsent Terminologies

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APPLIED CLINICAL TRIALS

eConsent -Why Language Matters!

*December 20, 2023*

*By Hilde Vanaken, Rebecca Zeising, Bethany Pryski and Liz Goodman*

***Fostering common eConsent terminologies enriches communication and understanding across all stakeholders***

Ask a group of industry professionals to describe 'eConsent' and you will get a variety of answers. Some of these answers may reflect a limited understanding of eConsent, and some may even propagate misconceptions around the use of eConsent. A recent poll at the DIA 2023 Global Annual Meeting's eConsent session[1] asked attendees about the use of eSignature: 78% responded that eConsent requires an electronic signature, propagating a common misconception around the varied uses of eConsent.

Widespread misunderstandings result in conflicting messages around the acceptance of eConsent, lack of clarity regarding study documents required for Health Authority and Ethics Committee submissions[2], and incomplete insights about the benefits and challenges posed to stakeholders.

Having harmonized terminologies to describe the platform and operational aspects of eConsent is critical to eliminate misconceptions and to enable transparency and a common understanding between all stakeholders. This was precisely the focus and intent when developing the Glossary of eConsent terms, one of the deliverables of the multi-stakeholder, non-profit European Forum for Good Clinical Practice (EFGCP) eConsent Initiative[3]. Where applicable, references to existing terminologies are incorporated in the glossary[4-15].

In addition, the glossary can also serve as a general knowledge base of key aspects to consider for sponsors and vendors when deploying eConsent. Of note, even within our group of industry experts from over 50 different organizations, we had several "eureka" moments as we learned from each

*Supporting article: eConsent Why Language Matters, Applied Clinical Trials Dec 2023, Author Hilde Vanaken et all.

# Defining Platform Aspects & Operational Aspects

**Glossary of eConsent Terms** with **64 eConsent Platform & Operational Aspects Terms**
Simple and clear terms with descriptions and examples

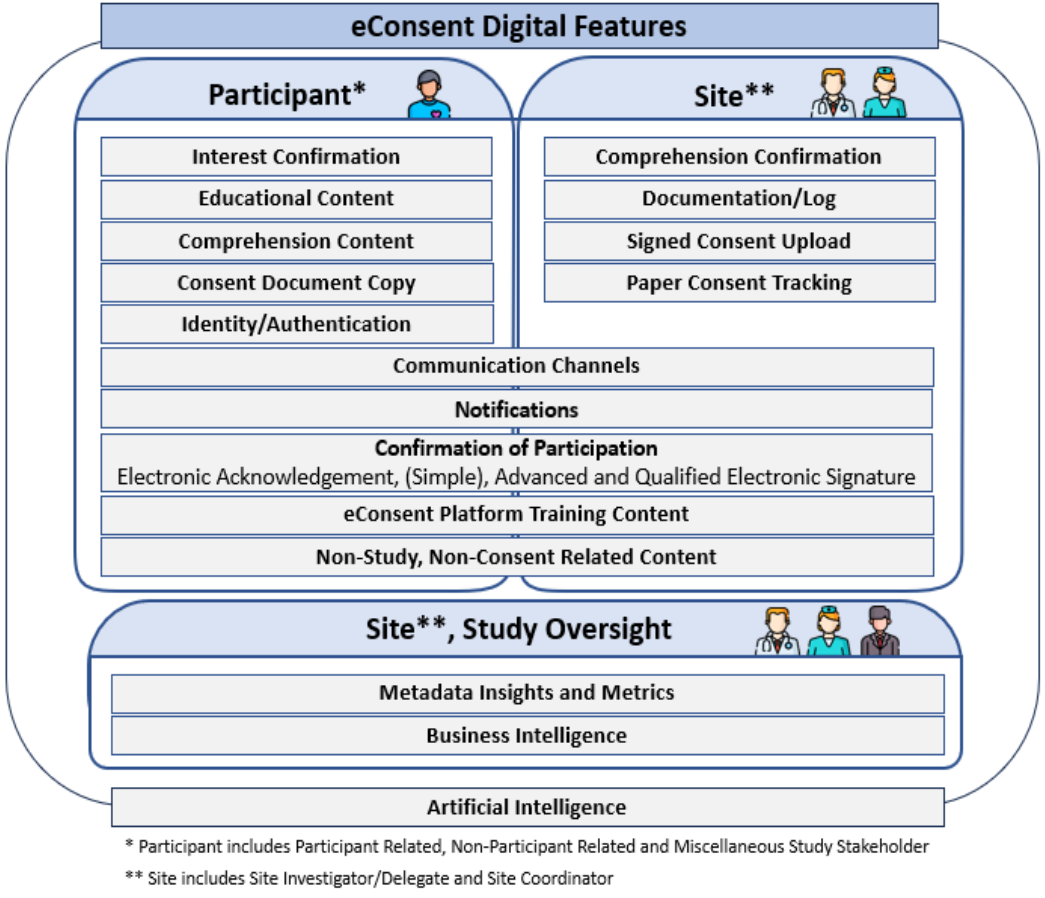
## eConsent Platform Aspects

| | | | |
|---|---|---|---|
| **Digital Features** | • Pre-Consent Acknowledgment<br>• Educational Content<br>• Comprehension Content<br>• Consent Document Copy<br>• Identity/Authentication<br>• Comprehension Confirmation<br>• Documentation/Log<br>• Signed Consent Upload<br>• Paper Consent Tracking<br>• Communication Channels<br>• Notifications<br>• Confirmation of Participation:<br>  • Electronic Acknowledgement<br>  • (Simple) Electronic Signature<br>  • Advanced Electronic Signature<br>  • Qualified Electronic Signature<br>• eConsent Platform Training Content<br>• Non-Study, Non-Consent Related Content<br>• Metadata Insights and Metrics<br>• Business Intelligence<br>• Artificial Intelligence | **Identifiers** | • Consent Document Identifier<br>• Consent Document Version Identifier<br>• Participant Identification Code<br>• Participant Token |
| | | **Consent Account** | • Participant Account<br>• Stakeholder Account |
| | | **Data Types** | • Personal Data<br>• Non-Personal Data<br>• Aggregated Metadata |
| | | **Data Privacy Clause/Agreement** | |
| | | **Compliance Documentation** | |
| | | **Validation Documentation** | |
| | | **Integrations** | |
| | | **Environments** | |

## eConsent Operational Aspects

| | | | |
|---|---|---|---|
| **Stakeholders** | • Participant<br>• Participant Related Stakeholder<br>• Non-Participant Related Stakeholder<br>• Miscellaneous Study Stakeholder<br>• Site Investigator/ Delegate<br>• Site Coordinator<br>• Study Oversight Stakeholder | **Consent Categorization** | • Main Consent Document<br>• Optional Consent Document<br>• Assent Document |
| | | **Consent workflow** | • Initial Consent<br>• Declined<br>• Reconsent<br>• Withdrawal<br>• Dynamic Consent |
| **Participant/ Site Location** | • In the Same Location<br>• Not in the Same Location<br>• Mixed Location | **Health Authority & Ethics Committee Submission** | |
| | | **Monitoring** | |
| **Timing of Signature** | • Discuss/Sign At the Same Time<br>• Discuss/Sign Not at the Same Time | **Auditing/Inspecting** | |
| | | **Training** | |
| **Device Deployment** | • Own Electronic Device<br>• Provisioned Electronic Device | **Support** | |
| **Data Access** | • Personal Data Access<br>• Non-Personal Data Access<br>• Edit Access<br>• Read Access | **Archiving/ Permanent Records** | • Site Consent Archiving<br>• Sponsor Consent Archiving<br>• Participant Consent Permanent records |

# Example – Digital Features as eConsent Platform Aspects Terms




* Participant includes Participant Related, Non-Participant Related and Miscellaneous Study Stakeholder

** Site includes Site Investigator/Delegate and Site Coordinator

**20 Digital Features Terms**

clustering individual digital feature examples based on their characteristics & commonalities

# Example - Some Digital Features In Detail

**Educational Content**

Digital **educational** consent content that **the participant can read, watch, hear**, etc. but that **does not allow an interaction** from the participant beyond consuming the content.

**Example**: Video

**Comprehension Content**

Digital **interactive** consent content where an **interaction of the participant might be, or is required,** to check comprehension.

**Example:** Quiz

**Comprehension Confirmation**

Digital **interactive** consent content for the **site investigator/ delegate** to **close the loop** on any questions, concerns, or knowledge gaps from the participant.

**Example**:
Site confirmation box

# Example – “Confirmation of Participation” Digital Feature Term

## 1.12. CONFIRMATION OF PARTICIPATION

### 1.12.1. ELECTRONIC ACKNOWLEDGEMENT

Description:
Digital methods used by the participant and site investigator/delegate, other than a signature or equivalent, to confirm participation in the study.

Examples:
Recording of names and tick boxes to confirm participation (no real signature), implicit consent unless opted out.

Primary stakeholders involved:
Participants, Sites.

### 1.12.2. (SIMPLE) ELECTRONIC

Description:
Any data in electronic f
is used by the signatory

No biometric data are
regulations and study ty

Other countries and regions migh
eSignature" but to describe the ac

Examples:
A handwritten signature drawn b
picture of a handwritten signatur

To illustrate different local/regi
electronic device” is a (simple) El
electronic signature by FDA regul

Primary stakeholders involved:
Participants, Sites.

*Examples on how to describe in detail are included in the Glossary of eConsent Terms*

### 1.12.3. ADVANCED ELECTRONIC SIGNATURE

Description:
sole control,
detectable (~
use the term
).

Examples:
Simple electronic signatures (see 1.12.2) combined with multi-factor authentication (e.g., registration code, security questions) or biometric data collection (e.g., fingerprints, facial recognition, retina scan, voice recognition).

Primary stakeholders involved:
Participants, Sites.

### 1.12.4. QUALIFIED ELECTRONIC SIGNATURE

Description:
An advanced electronic signature that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures. (~ European eIDAS regulation definition[7]).

Other countries and regions might use other categorizations; hence it is important to not simply use the term "Qualified eSignature" but to describe the actual implementation of the eSignature (see examples below).

Examples:
Locally approved/certified identity/signature applications and software, e.g., Belgian eID software/Itsme with linked electronic signature.

Primary stakeholders involved:
Participants, Sites.

## An eSignature is Not an eSignature Everywhere!

For example, a **“handwritten signature on an electronic device”**

**(Europe) eIDAS Simple eSignature**

**(US) NOT an eSignature**

Always **describe in detail** to ensure **correct understanding regardless of local/regional categorizations**

# Example – Other eConsent Platform Aspects Terms

**Business Intelligence**

Overviews of **eConsent status** for an individual participant or across participants at a site, country, regional and global level

Example:
Dashboards, Reports, Alerts on pending re-consents

**Data Privacy Clause / Agreement**

Legal disclaimer or privacy clause/agreement of the participant that their **personal data can be collected and/or used in the eConsent platform**. This agreement/clause can be part of the **consent content** and/or is collected **prior to the usage** of the eConsent platform itself.

Example:
Company and/or eConsent platform specific legal disclaimer

Data Privacy Clause is essential and must be included, although its placement can be flexible

# Example – eConsent Operational Aspects Terms

## 1. Stakeholders

### 1.1. PARTICIPANT

Description:
An individual who participates in a clinical study, either as a recipient of the investigational product(s) or as a control (Trial Participant definition of ICH GCP E6 (R3)[6]).

Other terms used are e.g., subject, trial participant.

Examples:
Patient, healthy volunteer, minor, etc.

### 1.2. PARTICIPANT RELATED STAKEHOLDER

Description:
An individual related to the par… the participant's participation in the clinical trial, … confirmation to participate.

Examples:
Legally authorized/acceptable rep…

### 1.3. NON-PARTICIPANT R…

Description:
An individual that is not related t… consent process. They may confirm the participan… in the consent process is separately documented.

Examples:
Translator, impartial witness

### 1.4. MISCELLANEOUS STUDY STAKEHOLDER

Description:
An individual that is directly or indirectly linked with the participant and may sign off on a separate document and/or their involvement is separately documented next to the consent process. They might not be part of the overall consent process.

Examples:
Pregnant female partner of a male participant, nursing care staff in retirement house not acting as a caregiver.

**Stakeholders Terms**

Different Stakeholders Can Play a Role

## 2. Participant/Site Location

### 2.1. AT THE SAME LOCATION

Description:
Refers to a participant and site investigator/delegate being physically at the same location to conduct all steps of the consent process.

Note - The location of both the participant (or the person acting on behalf of the participant) and the investigator is fundamental. Other stakeholders may also support the participant or investigator throughout this process (e.g. participant-related stakeholders, etc – see section B1) and may or may not be in the same location as the participant

Examples:
Investigator site (most common), participant's home or primary address (e.g., university home for a student), pharmacy, community health center.

### 2.2. NOT AT THE SAME LOCATION

Description:
Refers to a participan… steps of the consent process (interest conf… ss steps are done not in the same location, i…

Note - The location o… d the investigator is fundamental. Other … t this process (e.g. participant-related sta… as the participant

Examples:
Interaction is usually … examples are email, chatbot, video call), bu… tal feature involved).

**Location Terms**

"In person" is not the same for everyone

### 2.3. MIXED LOCATION

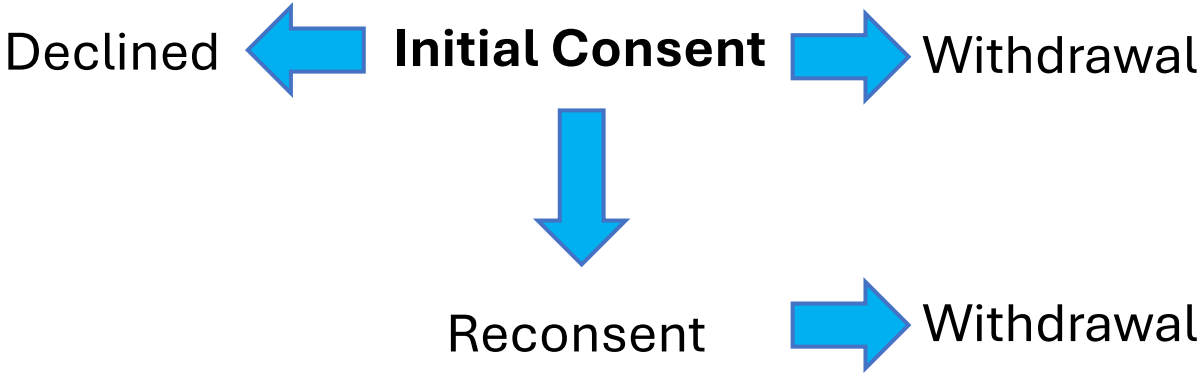
Description:
Refers to a participant and site investigator/delegate where some consent process steps are done in the same location, while others are not conducted in the same location.

Note - The location of both the participant (or the person acting on behalf of the participant) and the investigator is fundamental. Other stakeholders may also support the participant or investigator throughout this process (e.g. participant-related stakeholders, etc – see section B1) and may or may not be in the same location as the participant

Examples:
Sharing of the consent information with participant is done via email (Not in the Same Location) while the discussion with the site investigator/delegate is done at the investigator site (In the Same Location).

**Operational Aspects terms are often also applicable on the traditional consent process**

# Example – “Consent Workflows“ Terms as Operational Aspects




A withdrawal can only happen **after** a consent has been signed!

Another Workflow Term is “Dynamic Consent” (≠ eConsent)

# Glossary of eConsent Terms – Key Takeways

- eConsent = traditional consent process **supported** by one or more digital features
- eConsent is an **umbrella** term – **always specify the different aspects**!
- Your foundational tool: **Glossary** of eConsent terms
- Glossary describes the majority of eConsent platform and operational aspects containing the **term**, **description** and **examples** to foster the **right understanding for all stakeholders**.

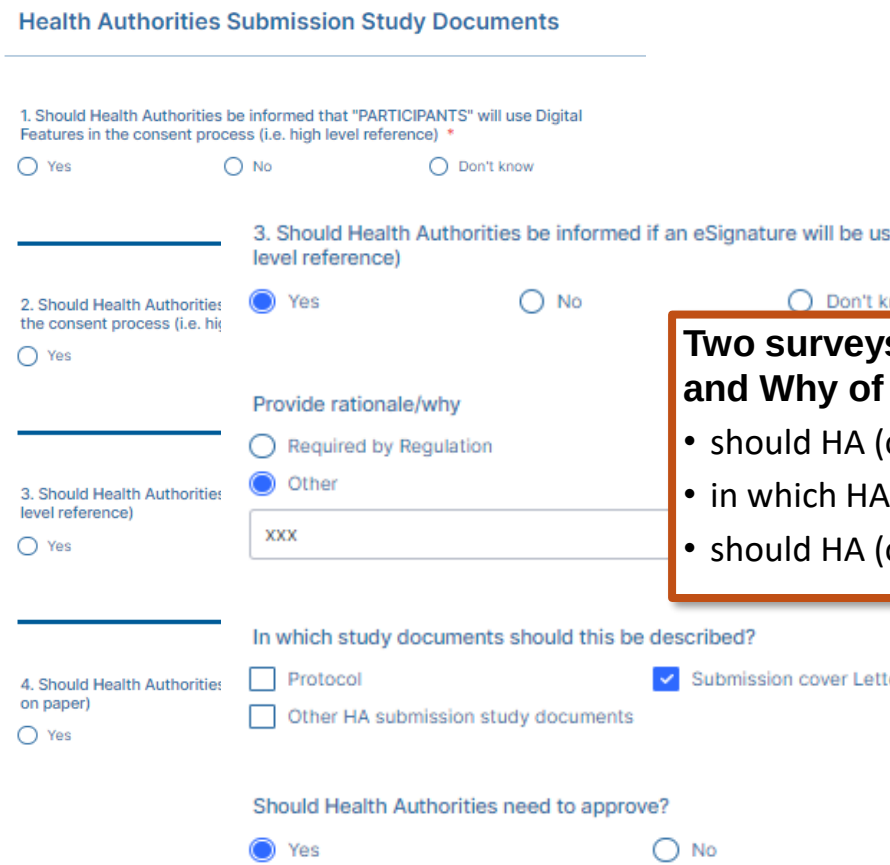
2B

# eConsent Study Documents Recommendations

**Study Docs Workstream**

*Presenter: Silvia Chia, Regulatory Sense Ltd.*

# Industry Perspective on ECs & HAs eConsent Submission Docs




**Two surveys (EC and HA) addressing the Who, What, Where and Why of various eConsent platform & operational aspects:**

- should HA (or EC) be informed or not + rationale?
- in which HA (or EC) submission doc should it be documented?
- should HA (or EC) approve or not?

# Broad Range of Questions – High Level Overview

| Category | Sub-Category | Should ECs (or HAs) be informed about the following aspects |
|---|---|---|
| eConsent Platform Aspects | Digital Features | Participant's use of digital features |
| | | Participant's type of digital features* |
| | | Site's use of digital features |
| | | Site's use of digital features |
| | eSignature/Wet Ink Signature | Use of eSignature |
| | | Type of eSignature* |
| | | Participants' access to a fully eSigned form* |
| | | Use of wet-ink signature |
| | | Electronic storage of wet-ink signed document* |
| | | Linkage of wet-ink signature with electronic consent record* |
| | Remote Identification Methods | Participants' remote identification methods |
| | Remote Consent withdrawal | Participants' remote consent withdrawal |
| | Electronic Data Storage | Electronic data storage of PII data |
| | | Electronic data storage of metadata metrics (non-PII data) |
| | Platform validation | Platform validation |
| | Platform integration | Platform integrations with study systems |
| | | Platform integrations with site systems |
| eConsent Operational Aspects | Location | Location of consent discussion |
| | Training | Participants' training |
| | | Sites' training |
| | Helpdesk | Participants' access to a helpdesk |
| | | Participants' helpdesk measures linked to privacy* |
| | | Sites' access to a helpdesk |
| | Device Deployment | Use of participants' own mobile device |
| | | Use of provisioned mobile device |
| | | Details of provisioned mobile device* |
| | Remote Monitor Access | Remote monitor access to PII data |
| | | Remote monitor access to non-PII data |

Same set of 28 questions for Ethics Committees and Health Authorities

# Broad Range of Questions – Some Examples

| Category | Sub-Category | Should ECs (or HAs) be informed about the following aspects |
|---|---|---|
| eConsent Platform Aspects | Digital Features | Participant's use of digital features |
| | | Participant's type of digital features* |
| | | Site's use of digital features |
| | | Site's use of digital features |
| | eSignature/Wet Ink Signature | Use of eSignature |
| | | Type of eSignature* |
| | | Participants' access to a fully eSigned form* |
| | | Use of wet-ink signature |
| | | Electronic storage of wet-ink signed document* |
| | | Linkage of wet-ink signature with electronic consent record* |
| | Remote Identification Methods | Participants' remote identification methods |
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| | | Use of provisioned mobile device |
| | | Details of provisioned mobile device* |
| | Remote Monitor Access | Remote monitor access to PII data |
| | | Remote monitor access to non-PII data |

Should HA (or ECs) be informed how the participant can access the fully eSigned form?

Should HA (or ECs) be informed if the eConsent tool is integrated with other study systems?

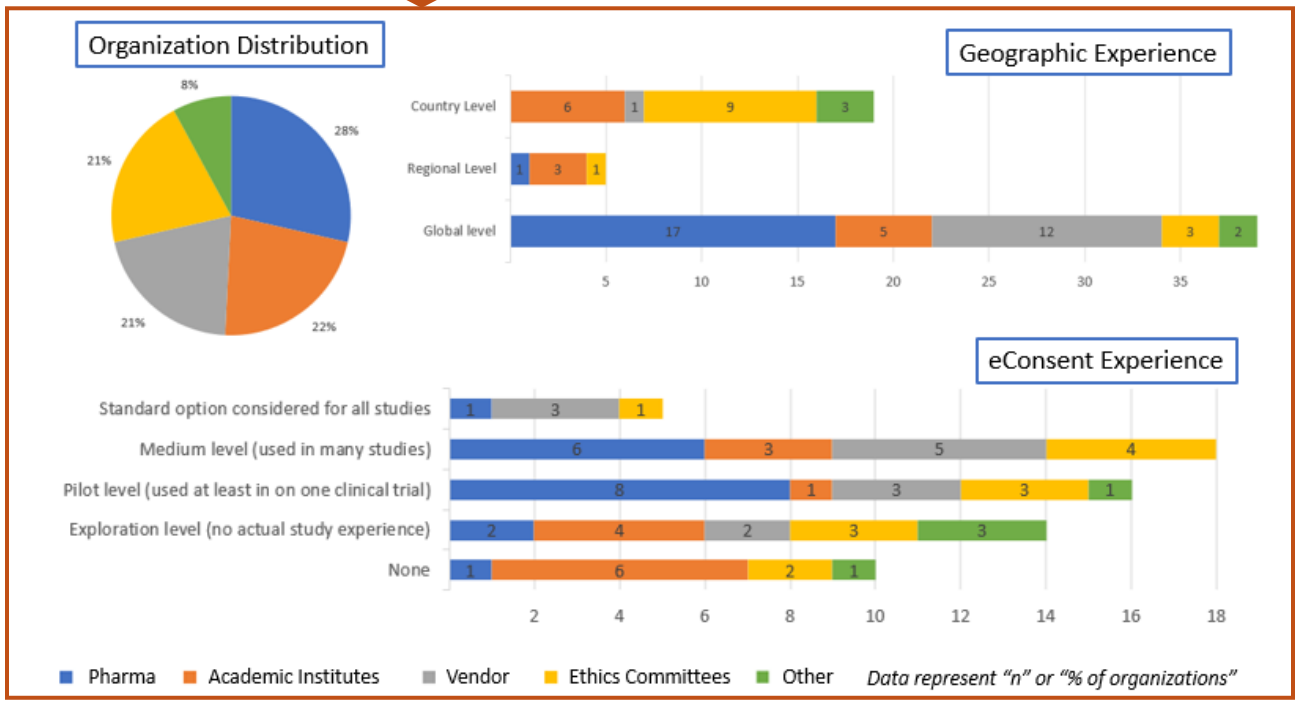
Should HA (or ECs) be informed if the participant is using his own mobile device?

Should HA (or ECs) be informed if the monitor has remote access to PII data?

# ECs and HAs eConsent Submission Docs Survey - Results

**EC Submission Docs Survey:**
**63 organizations**

**HA Submission Docs Survey:**
**58 organizations**




Similar organizational distribution but with few HAs included to compare with industry perspectives

* Supporting Article: Navigating eConsent Submissions: Who, What, Where and Why? Applied Clinical Trials Nov 2023, Author Hilde Vanaken et all.

# ECs Submission Docs Survey Results - ECs Should Be Informed (or not)

| Should ECs be informed about the following aspects? | All Organizations | | | | ECs responses alone | | | | All vs ECs |
|---|---|---|---|---|---|---|---|---|---|
| | # | ECs Should be Informed | ECs should NOT be informed | Don't know | # | ECs Should be Informed | ECs should NOT be informed | Don't know | Aligned/ not aligned |
| Participants' use of digital features (high-level reference) | 63 | 97% | 3% | 0% | 13 | 100% | 0% | 0% | Aligned |
| Participants' type of digital features* | *61* | *97%* | *3%* | *0%* | *13* | *100%* | *0%* | *0%* | *Aligned* |
| Sites' use of digital features (high-level reference) | 63 | 79% | 14% | 6% | 13 | 92% | 8% | 0% | Aligned |
| Sites' type of digital features* | *50* | *80%* | *16%* | *4%* | *12* | *100%* | *0%* | *0%* | *Aligned* |
| Use of eSignature (high-level reference) | 63 | 87% | 13% | 0% | 13 | 77% | 23% | 0% | Aligned |
| Type of eSignature* | *55* | *84%* | *11%* | *5%* | *10* | *80%* | *10%* | *10%* | *Aligned* |
| Participants' access to a fully eSigned form* | *55* | *93%* | *7%* | *0%* | *10* | *100%* | *0%* | *0%* | *Aligned* |
| Use of wet-ink signature | 63 | 63% | 37% | 0% | 13 | 62% | 38% | 0% | Aligned |
| Electronic storage of wet-ink signed document* | *40* | *68%* | *25%* | *8%* | *8* | *75%* | *25%* | *0%* | *Aligned* |
| Linkage of wet-ink signature with electronic consent record* | *40* | *63%* | *20%* | *18%* | *8* | *63%* | *25%* | *13%* | *Aligned* |
| Electronic data storage of PII data | 63 | 86% | 11% | 3% | 13 | 77% | 23% | 0% | Aligned |
| Electronic data storage of metadata metrics (non-PII data) | 63 | 48% | 44% | 8% | 13 | 46% | 46% | 8% | No consensus |
| Participants' remote identification methods | 63 | 83% | 11% | 6% | 13 | 85% | 8% | 8% | Aligned |
| Location of consent discussion | 63 | 79% | 19% | 2% | 13 | 100% | 0% | 0% | Aligned |
| Use of provisioned mobile device | 63 | 75% | 21% | 5% | 13 | 92% | 8% | 0% | Aligned |
| Details of provisioned mobile device* | *47* | *72%* | *17%* | *11%* | *12* | *83%* | *8%* | *8%* | *Aligned* |
| Use of participants' own mobile device | 63 | 65% | 25% | 10% | 13 | 85% | 15% | 0% | Aligned |
| Remote monitor access to PII data | 63 | 62% | 25% | 13% | 13 | 69% | 23% | 8% | Aligned |
| Remote monitor access to non-PII data | 63 | 33% | 40% | 27% | 13 | 46% | 38% | 15% | No consensus |
| Participants' remote consent withdrawal | 63 | 75% | 24% | 2% | 13 | 92% | 8% | 0% | Aligned |
| Platform validation | 63 | 56% | 38% | 6% | 13 | 46% | 46% | 8% | Not aligned |
| Platform integrations with study systems | 63 | 44% | 41% | 14% | 13 | 69% | 31% | 0% | Not aligned |
| Platform integrations with site systems | 63 | 52% | 37% | 11% | 13 | 69% | 23% | 8% | Aligned |
| Sites' training | 63 | 35% | 63% | 2% | 13 | 38% | 54% | 8% | Aligned |
| Participants' training | 63 | 79% | 16% | 5% | 13 | 69% | 23% | 8% | Aligned |
| Sites' access to a helpdesk | 63 | 29% | 63% | 8% | 13 | 31% | 62% | 8% | Aligned |
| Participants' access to a helpdesk | 63 | 75% | 17% | 8% | 13 | 77% | 15% | 8% | Aligned |
| Participants' helpdesk measures linked to privacy* | *47* | *68%* | *19%* | *13%* | *10* | *70%* | *20%* | *10%* | *Aligned* |

| High consensus (+70% of organizations) | Medium consensus (between 60-70% of organizations) | Low consensus (between 50-60% of organizations) | No consensus (less 50% of organizations) |
|---|---|---|---|

- **Overall opinion that ECs should be informed** of **MOST aspects** but
  - various level of consensus
  - not one single question with 100% consensus
- **Overall, aligned opinions on most aspects (80%!)** between **industry** and **Ethics Committees**

# Examples - Various Level of Consensus

## Ethics Committees Should Be Informed

### High Consensus
**(+70% of Organizations)**

- Participant's use of digital features, use of eSignature, remote consent withdrawal, remote identification methods, location of consent discussion, training, and access to helpdesk
- Participants'/sites' use of a provisioned mobile device
- Sites' use of digital features
- Electronic data storage of PII data

### Medium Consensus
**(60-70% of Organizations)**

- Participant's use of wet-ink signature and electronic storage and linkage with digital features, use of own mobile device
- Remote monitor access to PII data

### Low Consensus
**(50-60% of Organizations)**

- Platform validation, platform integration with site systems

## Ethics Committees Should NOT Be Informed

- Sites' training, sites' access to helpdesk

## No Consensus On ECs To Be Informed or Not

- Electronic data storage of metadata metrics (non-PII data)
- Platform integrations with study systems and site systems.
- Remote monitor access to non-PII data.

# ECs Submission Docs Results - “Protocol”

| % of organizations per organization type that selected "Protocol" | | | | | |
|---|---|---|---|---|---|
| eConsent Platform and Operational Aspects | All | EC | Pharma | Acad Instit | Vendor |
| Participants' use of digital features (high-level reference) | 64% | 69% | 41% | 93% | 50% |
| Participants' type of digital features* | 49% | 69% | 24% | 77% | 9% |
| Sites' use of digital features (high-level reference) | 58% | 58% | 42% | 75% | 44% |
| Sites' type of digital features* | 45% | 58% | 30% | 56% | 0% |
| Use of eSignature (high-level reference) | 47% | 50% | 25% | 77% | 36% |
| Type of eSignature* | 37% | 50% | 29% | 45% | 25% |
| Participants' access to fully eSigned form* | 29% | 40% | 13% | 55% | 10% |
| Use of wet-ink signature | 28% | 50% | 20% | 33% | 11% |
| Electronic storage of wet-ink signed document* | 37% | 50% | 17% | 50% | 20% |
| Linkage of wet-ink signature with electronic consent record* | 36% | 60% | 17% | 50% | 20% |
| Electronic data storage of PII data | 50% | 80% | 27% | 83% | 25% |
| Electronic data storage of non-PII data | 47% | 83% | 33% | 56% | 0% |
| Participants' remote identification methods | 46% | 64% | 23% | 73% | 33% |
| Location of consent discussion | 64% | 69% | 33% | 100% | 60% |
| Use of provisioned mobile device | 64% | 58% | 54% | 92% | 33% |
| Details of provisioned mobile device* | 32% | 30% | 33% | 38% | 0% |
| Use of participants' own mobile device | 44% | 36% | 50% | 43% | 33% |
| Remote monitor access to PII data | 67% | 56% | 58% | 100% | 50% |
| Remote monitor access to non-PII data | 76% | 67% | 75% | 100% | 33% |
| Participants' remote consent withdrawal | 47% | 42% | 45% | 88% | 18% |
| Platform validation | 51% | 33% | 42% | 78% | 25% |
| Platform integrations with study systems | 75% | 67% | 57% | 86% | 33% |
| Platform integrations with site systems | 52% | 44% | 56% | 56% | 25% |
| Sites' training | 50% | 40% | 60% | 67% | 40% |
| Participants' training | 34% | 44% | 20% | 64% | 17% |
| Sites' access to a helpdesk | 44% | 25% | 60% | 80% | 0% |
| Participants' access to a helpdesk | 28% | 20% | 27% | 44% | 22% |
| Participants' helpdesk measures linked to privacy* | 31% | 29% | 22% | 67% | 14% |

| Multiple Answer Categorization | | |
|---|---|---|
| High (+70% of organizations) | Partial (between 25-50% of organizations) | Not selected (0%) |
| Moderate (between 50-70% of organizations) | Low (less 25% of organizations) | |

- **Protocol selected** as the submission document to reflect **ALL aspects** but
  - high variation between aspects and consensus level
  - not one single question with 100% consensus
- **Academic Institutes** and **Ethics Committees** had overall **strong preference for the protocol**

# HA Submission Docs Results – HAs Should NOT be Informed

| Organization Type | % of Core Questions That HAs Should be Informed, Not Informed or No Consensus | | |
|---|---|---|---|
| | Inform | Not Inform | No Consensus |
| **All** (n = 58) | 15% | **75%** | 10% |
| **HAs** (n = 3) | **80%** | 10% | 10% |
| **ECs** (n =2) | 0% | **90%** | 10% |
| **Pharma** (n =17) | 5% | **85%** | 10% |
| **Academic Institutes** (n =10) | 40% | **50%** | 10% |
| **Vendors** (n =20) | 20% | **75%** | 5% |
| **Other** (n =6) | 30% | 35% | 35% |

- **Overall opinion that HAs Should NOT be informed** of **MOST aspects** but
  - various level of consensus
  - not one single question with 100% consensus
- **Limited alignment (25%!)** on most aspects between **industry** and **Health Authorities**

# eConsent Study Documents Recommendations

EFGCP

Where Science, Quality & Ethics Meet

EFGCP eConsent Initiative

*eConsent Study Documents Recommendations*

5 July 2024

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Recommendations created for

**9 study documents**

- Protocol
- Health Authority Submission Cover Letter
- Ethics Committees Submission Cover Letter
- Participant-related eConsent Documents
- Informed Consent Document
- Site eConsent Document
- Monitoring Plan
- Data Management Plan
- Platform/Vendor Due Diligence Documents

**More than 50 different eConsent Platform and Operational Aspects have been considered**

# Example – eConsent Recommendations for Protocol

## 3. PROTOCOL

### 3.1. Description

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents (Definition from ICH GCP E6 R3)[2].

### 3.2. eConsent Recommendations for Protocol

| Aspects | Categories | Sub-Categories | Category Detail | Description |
|---|---|---|---|---|
| eConsent Platform Aspects | Digital Features | Participants' Digital Features | High Level | High level description/reference of the digital features that a participant may have/use to support the consent process (eConsent). |
| | | Participants'/ sites' Confirmation of Participation | High Level | High level description/reference of the digital features that a participant/site may have/use to confirm his/her participation in the consent process: e.g. an eIDAS eSignature will/can be used to confirm participant's participation in the consent process. |
| | | Participants' Remote Identity/Authentication | | Description of methods used to remotely identify/authenticate the participant during the consent process: e.g. locally approved/certified identity devices/systems, digital sharing of participant's identity card, two-factor authentication, etc. |
| eConsent Operational Aspects | Participant/Site Location | Full Remote Consent Process | High Level | High level reference in case of absence of any physical interaction between the participant and site investigator for the consent process. |
| | Consent Workflow | Participants' Remote Withdrawal Process | | Description that a participant can remotely revoke his/her decision to participate in a clinical study via the eConsent platform. |
| The term "Participant" may also apply to other stakeholders involved (e.g. legal authorized representatives, witness, translator). | | | | |

There might be cases where sites are using their own eConsent platform, the sponsor will need to consider whether this detail should be part of the protocol or be documented somewhere else.

- Recommendations combine **survey results** and **practical implications** (e.g. limit unnecessary complexities).
- **Variations might exist** (e.g. study, #eConsent aspects used). **There is no one-size-fits-all study document recommendation.**

# Study Documents Recommendations – Key Takeways

Many uncertainties and different opinions exist on what Ethics Committees and Health Authorities should be informed about (or not), and how other stakeholders should indiate the various eConsent aspects within the study documents

**eConsent Study Documents Recommendations**

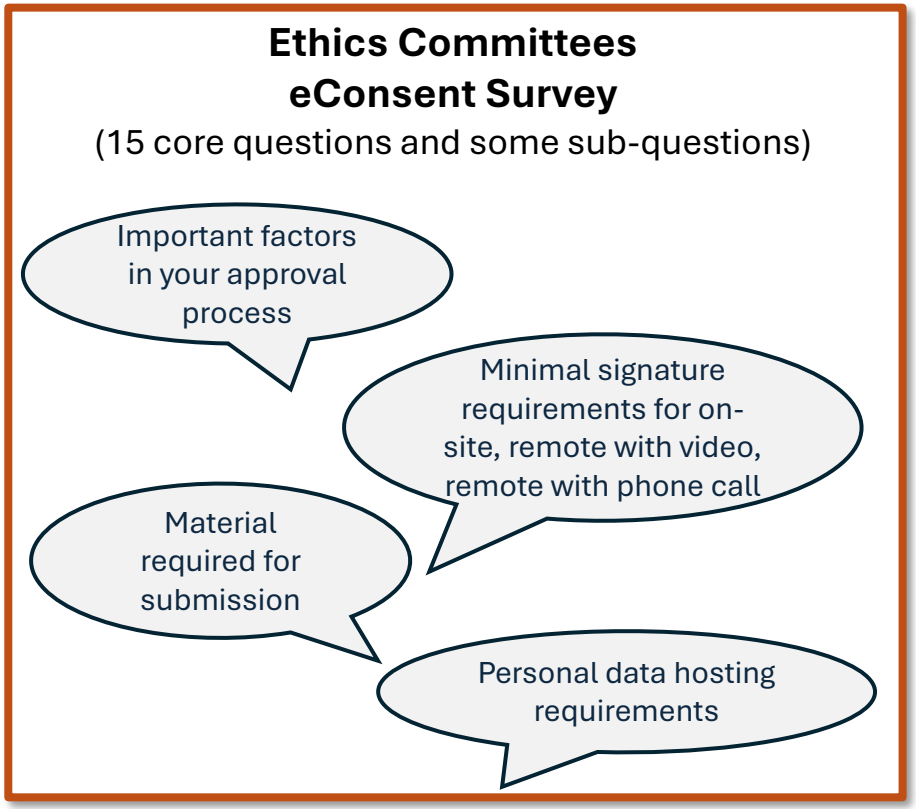
2C

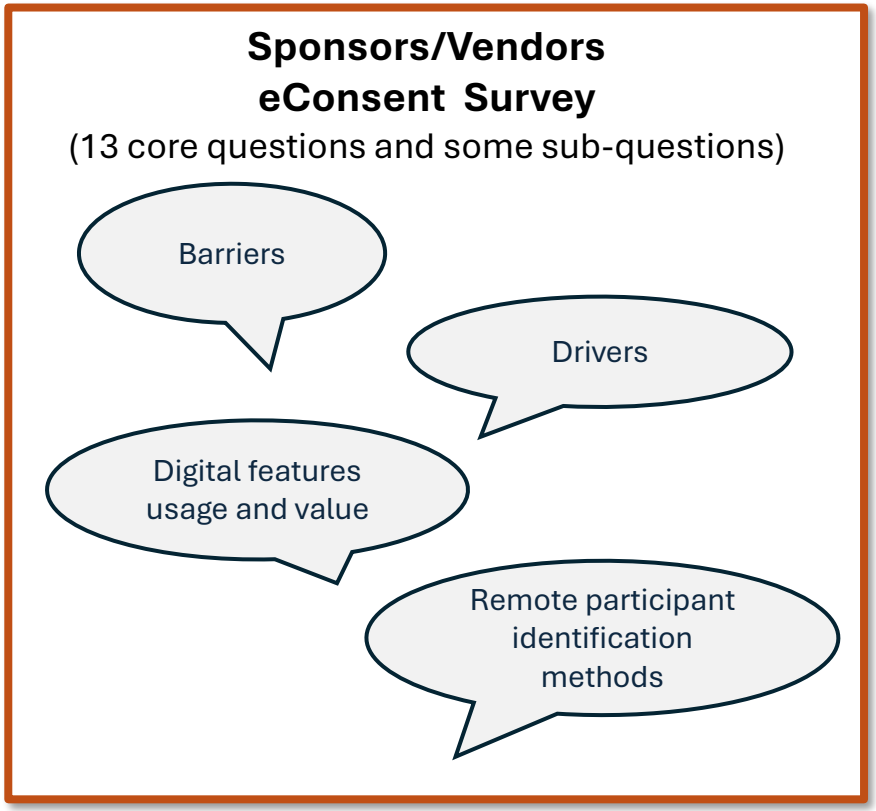
# Insights in Ethics Committees, Sponsors and Vendors Expectations

**Database Workstream**

*Presenter: Susie Song, Biogen*

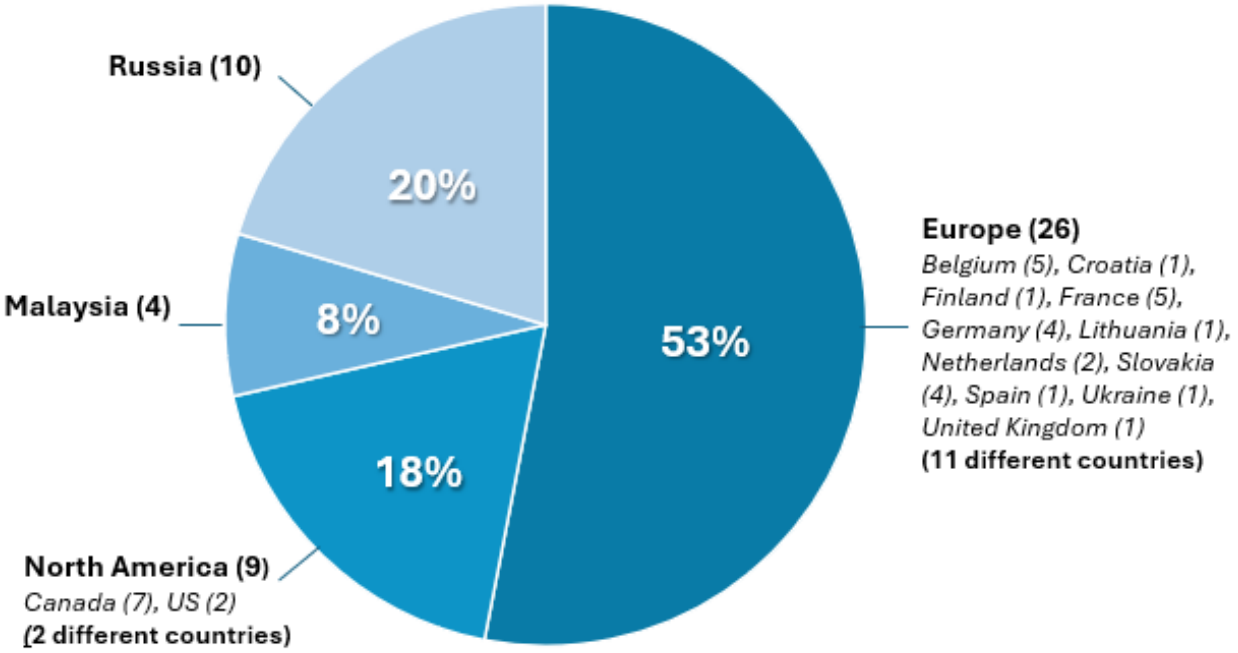
# ECs, Sponsors & Vendors eConsent Perspectives & Expectations



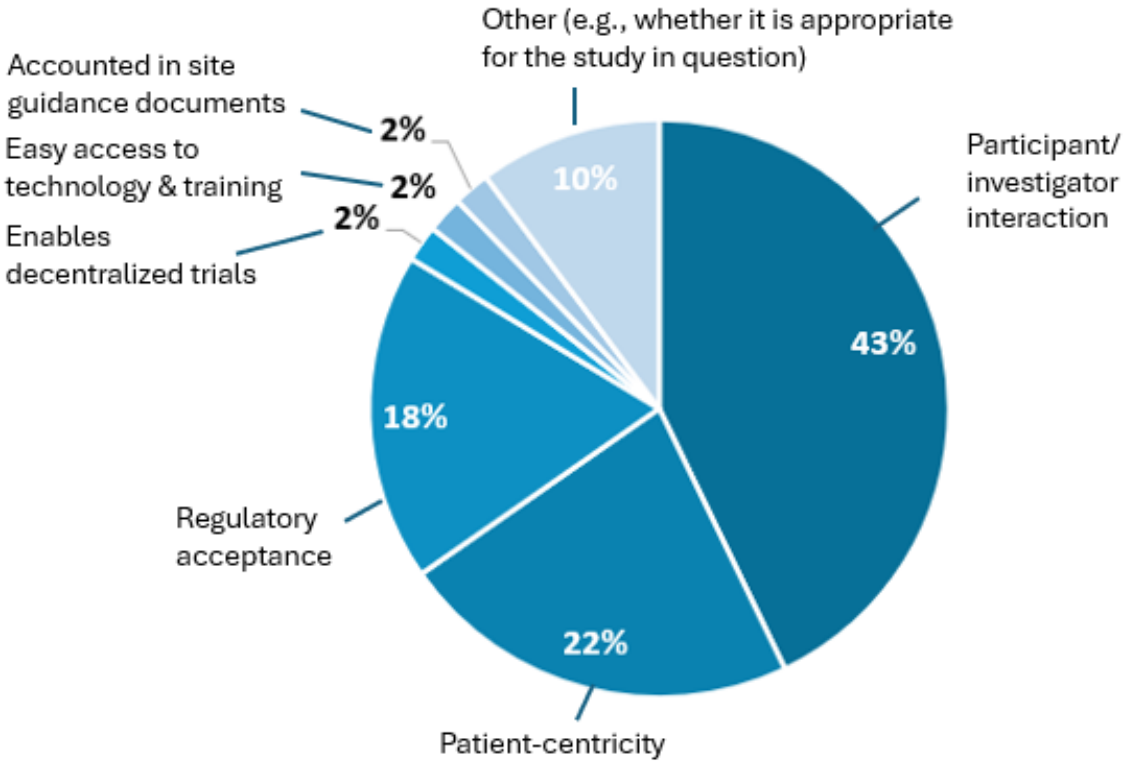

* Supporting Article: Understanding Acceptability of eConsent from a Global, Ethical and Industry Perspective. Applied Clinical Trials Oct 2024, Author Hilde Vanaken et all.

# Ethics Committees eConsent Survey - Results




- **49 ECs** respondents of **15 different countries**
- **35% of ECs have never been asked to review an eConsent**

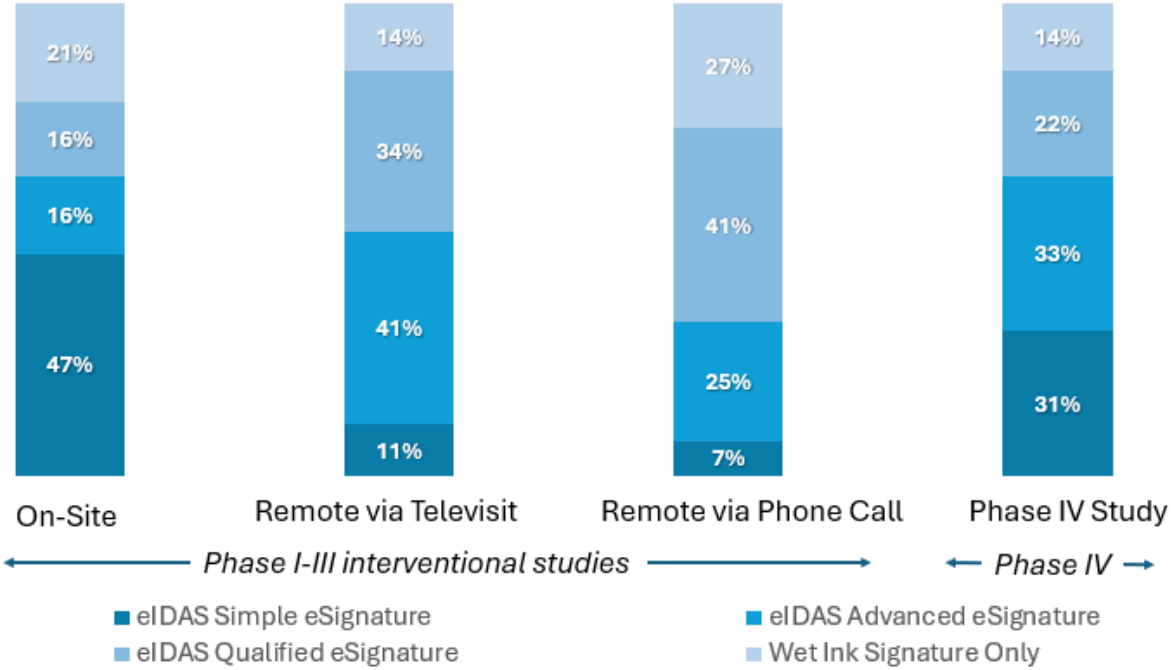
# Ethics Committees eConsent Survey - Results




**Preserving the interaction between participant and investigator** was reported as the most important approval factor for Ethics Committees

# Ethics Committees eConsent Survey - Results

**Minimal Signature Requirements (eIDAS categories, wet-ink) for eConsent**




- Overall, **high acceptance** for eSignatures by ECs!
- **More stringent** eIDAS signature requirements when **moving from on-site to remote workflows** to include identity verification.

# Ethics Committees eConsent Survey - Results

| | North American ECs (#= 9) | European ECs (# = 26) |
|---|---|---|
| Experience with eConsent | 78% | 65% |
| Personal Data Must be Stored On Site | 44% | 77% |
| Paper Option is Needed | 78% | 65% |
| Minimal Consent Signature Requirement On Site: | | |
| - Simple eSignature | 33% | 53% |
| - Advanced eSignature | 33% | 12% |
| - Qualified eSignature | 11% | 24% |
| - Wet Ink Signature | 22% | 13% |

**Regional differences exist** between **European and North American** Ethics Committees, **but some are less profound or not as expected**

# Ethics Committees eConsent Survey - Results

| | North American ECs (#= 9) | European ECs (# = 26) |
|---|---|---|
| **Experience with eConsent** | 78% | 65% |
| **Personal Data Must be Stored On Site** | 44% | 77% |
| **Paper Option is Needed** | 78% | 65% |
| **Minimal Consent Signature Requirement On Site:** | | |
| **- Simple eSignature** | 33% | 53% |
| **- Advanced eSignature** | 33% | 12% |
| **- Qualified eSignature** | 11% | 24% |
| **- Wet Ink Signature** | 22% | 13% |

**Higher experience** of North American ECs

**Higher preference** of European ECs to **store electronically collected personal data on-site**

# Ethics Committees eConsent Survey - Results

| | North American ECs (#= 9) | European ECs (# = 26) |
|---|---|---|
| Experience with eConsent | 78% | 65% |
| Personal Data Must be Stored On Site | 44% | 77% |
| Paper Option is Needed | 78% | 65% |
| Minimal Consent Signature Requirement On Site: | | |
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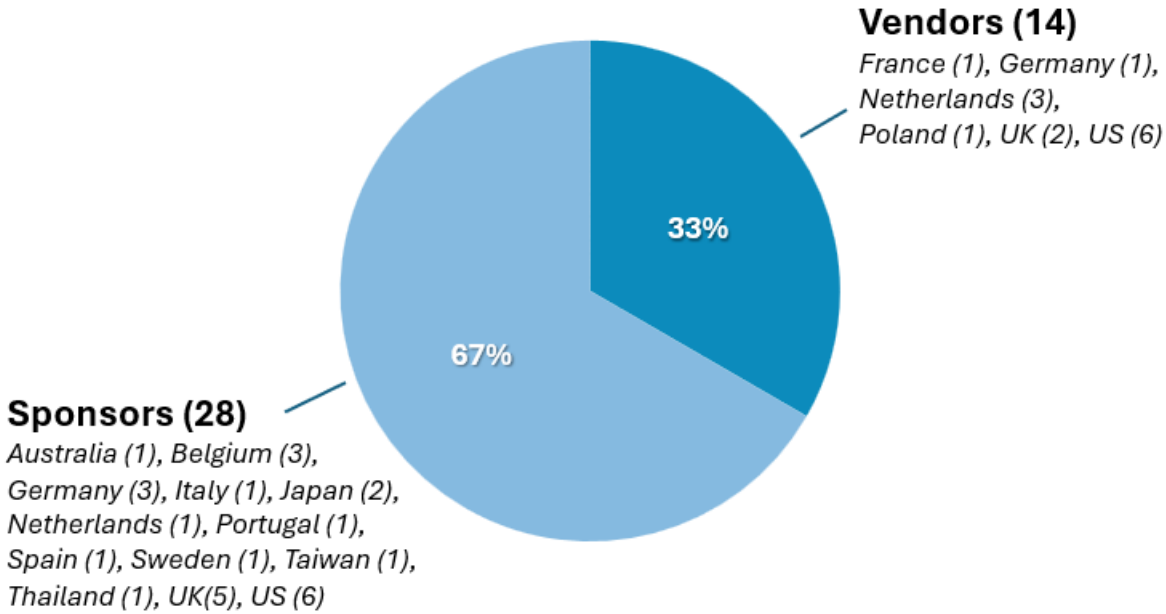
| - Advanced eSignature | 33% | 12% |
| - Qualified eSignature | 11% | 24% |
| - Wet Ink Signature | 22% | 13% |

**Higher preference** of North American ECs to always provide a **paper option**

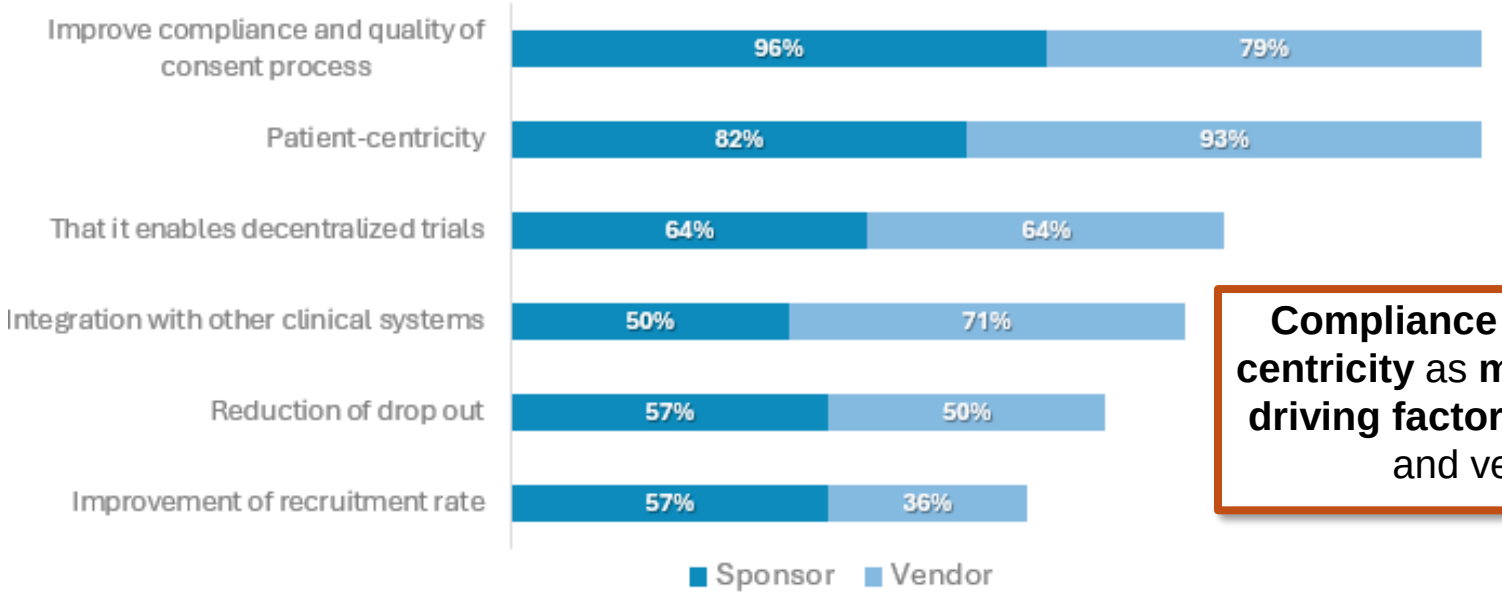
**Higher preference** of North American ECs to **use wet-ink signature** in case of on-site eConsent

# Sponsor/Vendor eConsent Survey - Results




- **42** Sponsor/Vendor respondents of **16 different countries**
- **26% with no experience with eConsent** (36% sponsors, 7% vendors)

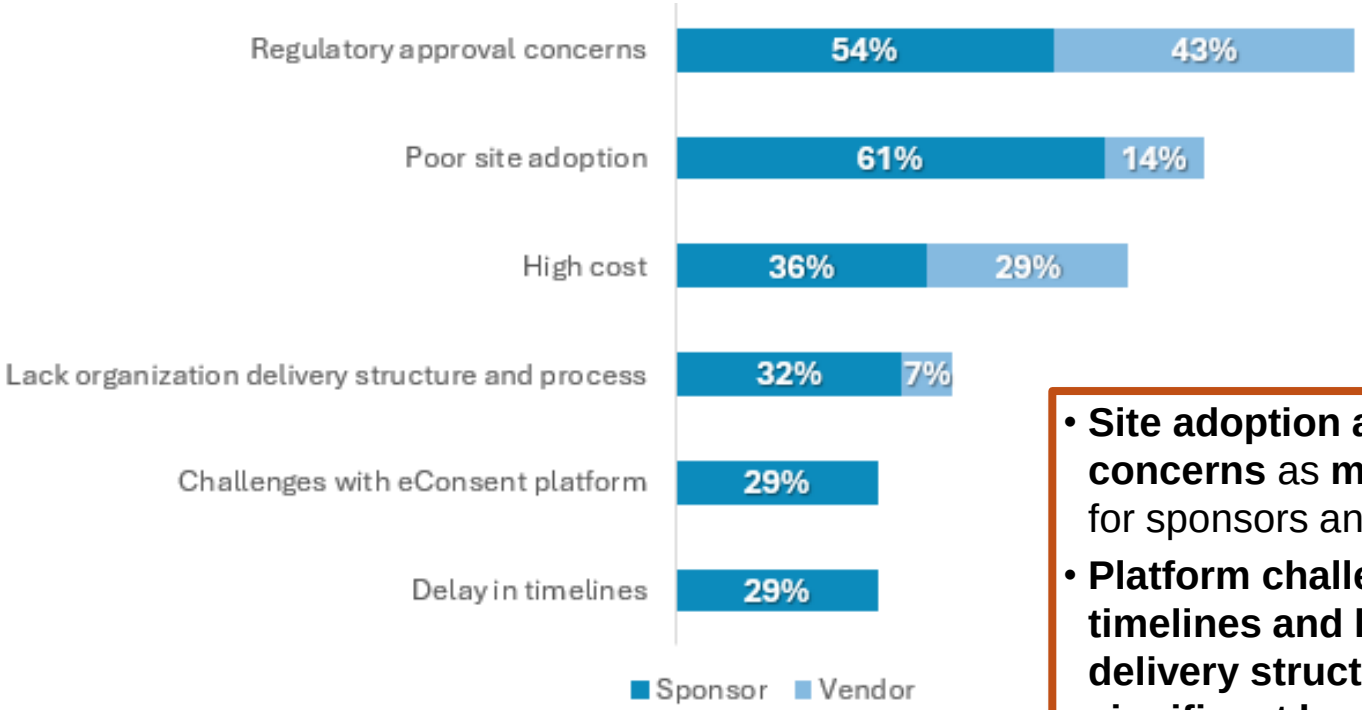
# Sponsors/Vendors eConsent Survey - Results




**Compliance and patient-centricity** as **most important driving factors** for sponsors and vendors

# sponsors (or vendors) that scored the factor as an "essential/very important" versus total # sponsors (or vendors)

# Sponsors/Vendors eConsent Survey - Results




- **Site adoption and regulatory approval concerns** as **most significant barriers** for sponsors and vendors
- **Platform challenges, delay in timelines and lack organization delivery structure** seen as additional **significant barriers by sponsor**

# Ethics Committees, Sponsors and Vendors - Key Takeways

- **Ethics Committees are supportive for eConsent, but key is to**
  - Ensure the participant-investigator interaction is not impacted
  - Ensure a paper option is available
  - Ensure participant data and identity are securely stored and protected

- There might be **different views between stakeholders**, such as e.g., perceived barriers of sponsors versus vendors

**Transparent and direct interaction** with the **involved stakeholders** is **key**

2D

# eConsent Fit-for-Purpose Study Framework

**Pharma, Vendor & Academic Institutes Workstreams**

*Pharma WS presenter: Bethany Pryski, Pfizer*

# To Date, eConsent Adoption Is Limited

## There is No One-Size-Fits-All eConsent

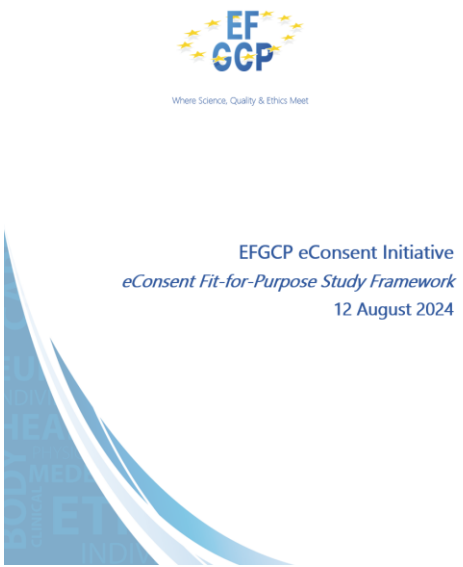
Each indication, each study, each site, each participant might have different needs

## Lack of Concrete eConsent Study Data

Lack of effective, comparable metrics and measurements, limited insight in analysis methodology and aspects used

* In addition to the other challenges addressed already such as the disconnects in understanding

# eConsent Fit-for-Purpose Study Framework

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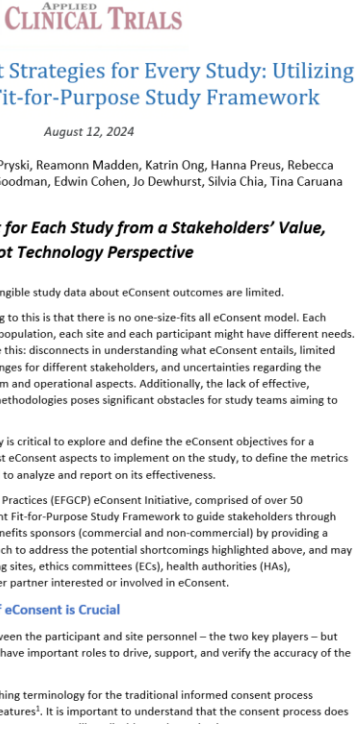


APPLIED CLINICAL TRIALS

## Effective eConsent Strategies for Every Study: Utilizing the eConsent Fit-for-Purpose Study Framework

*August 12, 2024*

By Hilde Vanaken, Bethany Pryski, Reamonn Madden, Katrin Ong, Hanna Preus, Rebecca Zeising, Petra Ochabova, Liz Goodman, Edwin Cohen, Jo Dewhurst, Silvia Chia, Tina Caruana

***Designing eConsent for Each Study from a Stakeholders' Value, Not Technology Perspective***

To date, eConsent adoption and tangible study data about eConsent outcomes are limited.

The most crucial factor contributing to this is that there is no one-size-fits all eConsent model. Each indication, each study, each study population, each site and each participant might have different needs. Multiple factors further complicate this: disconnects in understanding what eConsent entails, limited insight into the benefits and challenges for different stakeholders, and uncertainties regarding the impact of various eConsent platform and operational aspects. Additionally, the lack of effective, comparable metrics and analysis methodologies poses significant obstacles for study teams aiming to deploy eConsent.

A step-by-step evaluation per study is critical to explore and define the eConsent objectives for a particular study, to identify the best eConsent aspects to implement on the study, to define the metrics and measurements of success, and to analyze and report on its effectiveness.

The European Forum Good Clinical Practices (EFGCP) eConsent Initiative, comprised of over 50 companies, developed the eConsent Fit-for-Purpose Study Framework to guide stakeholders through this evaluation. This framework benefits sponsors (commercial and non-commercial) by providing a structured and harmonized approach to address the potential shortcomings highlighted above, and may benefit other stakeholders including sites, ethics committees (ECs), health authorities (HAs), participants, vendors, and any other partner interested or involved in eConsent.

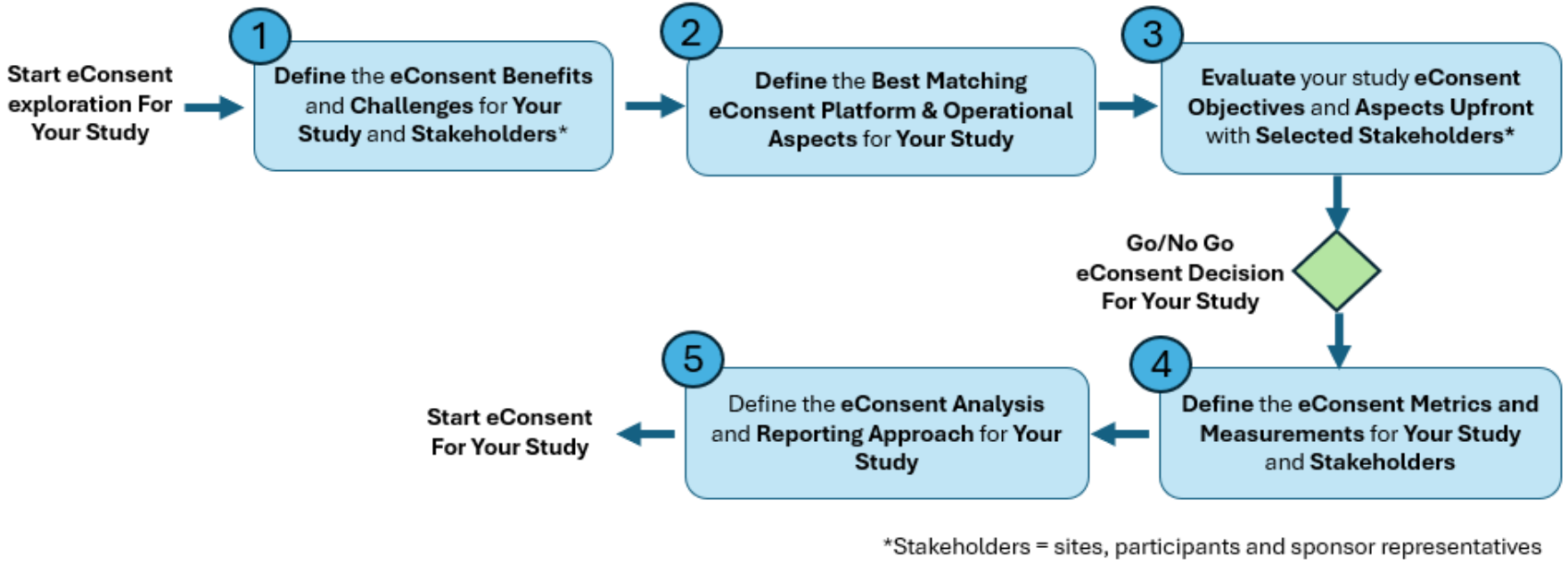
### A Common Understanding of eConsent is Crucial

Informed consent is a process between the participant and site personnel – the two key players – but the sponsor and other parties also have important roles to drive, support, and verify the accuracy of the process.

The term 'eConsent' is the overarching terminology for the traditional informed consent process supported by one or more digital features[1]. It is important to understand that the consent process does

* Supporting Article: Effective eConsent Strategies for Every Study. Applied Clinical Trials Aug 2024, Author Hilde Vanaken et all.

# A 5-Step Process Flow To Enable a Fit-for-Purpose for Your Study




*Depending on the organization strategy, variations might exist in the overall process flow.*

# Step 1A – Define the eConsent Benefits For Your Study

| CROSS-STAKEHOLDER ECONSENT BENEFITS IMPACT OVERVIEW | | | |
|---|---|---|---|
| **POTENTIAL ECONSENT BENEFITS** | **SPONSOR** | **SITE** | **PARTICIPANT** |
| Enhancing participant preparedness in advance | +++ | +++ | +++ |
| Improving consistent and complex information sharing | +++ | +++ | +++ |
| Enhancing access, recruitment and diversity | +++ | +++ | +++ |
| Enhancing autonomy for vulnerable/specialized participant groups | +++ | +++ | +++ |
| Improving participants' understanding | +++ | +++ | +++ |
| Reducing participants' dropouts | +++ | +++ | +++ |
| Enhancing the ability for flexible communication channels | +++ | +++ | +++ |
| Increasing the quality of consent data | +++ | +++ | + |
| Improving compliance with the consent process | +++ | +++ | + |
| Improving tracking and insights into optional consents | +++ | +++ | + |
| Improving oversight and real-time insights | +++ | +++ | / |
| Enabling integration with other systems | +++ | +++ | / |
| Reducing on-site consent auditing and inspection activities | +++ | +++ | / |
| Reducing on-site consent monitoring activities | +++ | + | / |
| Enhancing continuous improvement of consent content | +++ | + | + |
| Supporting sites to have a more tailored discussion with the participant | + | +++ | +++ |
| Improving consent storage | + | +++ | +++ |
| Improving consent archival for sites | + | +++ | / |

| *Impact Legend – impact can be direct or indirect* | |
|---|---|
| +++ | *The benefit has a **significant impact** on the stakeholder.* |
| + | *The benefit has **some impact** on the stakeholder.* |
| / | *The benefit has **no impact** on the stakeholder.* |

- **18 potential eConsent benefits** and **impact on sponsor, site & participant**
- All **potential benefits** have an impact on both **sponsor and sites**, either **directly or indirectly**

# Potential eConsent Benefits –Some Examples

**Sponsor: +++**
Site: +/++/+++;
Participant: /

- Reducing on-site consent monitoring activities
- Improving oversight and real-time insights
- Increasing the quality of consent data
- Enabling integrations with other systems

**Site: +++**
Sponsor: +/++/+++;
Participant: +/+++

- Improving tracking and insight into optional consents
- Improving consent storage and archival
- Improving compliance with the consent process
- Supporting sites to have a more tailored discussion with the participant

**Participant: +++**
Site: +++
Sponsor: +++

- Enhancing participant preparedness in advance
- Improving consistent and complex information sharing
- Enhancing access, recruitment and diversity
- Improving participant's understanding

# Step 1B – Define the eConsent Challenges For Your Study

| CROSS STAKEHOLDER ECONSENT CHALLENGES IMPACT OVERVIEW | | | |
|---|---|---|---|
| **POTENTIAL ECONSENT CHALLENGES** | **SPONSOR** | **SITE** | **PARTICIPANT** |
| Resisting technology adoption by sites | +++ | +++ | +++ |
| Resisting technology adoption and/or limited technology skills of participants | +++ | +++ | +++ |
| Navigating the complex usability of eConsent platforms | +++ | +++ | +++ |
| Navigating a variety of electronic devices | +++ | +++ | +++ |
| Dealing with incompatible IT infrastructure on the site | +++ | +++ | +++ |
| Extending submission and approval timelines | +++ | +++ | + |
| Extending the development timelines | +++ | +++ | + |
| Correcting errors in linkage EDC ID and Consent ID | +++ | +++ | / |
| Navigating the wide range of eConsent platforms | +++ | +++ | / |
| Increasing administrative workload and training | +++ | +++ | / |
| Increasing heterogenous oversight and deployment | +++ | +++ | / |
| Increasing consent data review activities | +++ | +++ | / |
| Limiting availability of integrated systems | +++ | +++ | / |
| Increasing complexity to navigate multiple stakeholders | +++ | + | / |
| Increasing impact on budget and resources | +++ | + | / |
| Impacting site relationships with participants | + | +++ | +++ |

| *Impact Legend – impact can be direct or indirect* | |
|---|---|
| *+++* | *The challenge has **a significant impact** on the stakeholder that **needs consideration and action to be taken.*** |
| *+* | *The challenge has **some impact** on the stakeholder that **needs consideration and action to be taken.*** |
| */* | *The challenge has **no impact** on the stakeholder.* |

- **16 potential eConsent** challenges and impact on sponsor, site & participant
- **Challenges are not the same as risk** and **are not meant to discourage** but are **important to consider and proactively mitigate**

# Potential eConsent Challenges – Some examples

| CROSS STAKEHOLDER ECONSENT CHALLENGES IMPACT OVERVIEW | | | |
|---|---|---|---|
| POTENTIAL ECONSENT CHALLENGES | SPONSOR | SITE | PARTICIPANT |
| Resisting technology adoption by sites | +++ | +++ | +++ |
| Resisting technology adoption and/or limited technology skills of participants | +++ | +++ | +++ |
| Navigating the complex usability of eConsent platforms | +++ | +++ | +++ |
| Navigating a variety of electronic devices | +++ | +++ | +++ |
| Dealing with incompatible IT infrastructure on the site | +++ | +++ | +++ |
| Extending submission and approval timelines | +++ | +++ | + |
| Extending the development timelines | +++ | +++ | + |
| Correcting errors in linkage EDC ID and Consent ID | +++ | +++ | / |
| Navigating the wide range of eConsent platforms | +++ | +++ | / |
| ncreasing administrative workload and training | +++ | +++ | / |
| ncreasing heterogenous oversight and deployment | +++ | +++ | / |
| Increasing consent data review activities | +++ | +++ | / |
| Limiting availability of integrated systems | +++ | +++ | / |
| Increasing complexity to navigate multiple stakeholders | +++ | + | / |
| ncreasing impact on budget and resources | +++ | + | / |
| Impacting site relationships with participants | + | +++ | +++ |

→ Technology adoption and digital skills

→ Impact on timelines

→ Impact on workload

→ Impact on budget

Note – some benefits can also be present a challenge.

# Step 2 – Define the Best Matching eConsent Aspects For Your Study

| | Pre-Consent Acknowledgment | Educational content | Comprehension Content | Comprehension Confirmation | Communication channels | Consent Document Copy | Identity/authentication | Documentation/Log | Signed Consent Upload | Paper Consent Tracking | Confirmation of Participation | Metadata Insights and Metrics | Business Intelligence | Notifications |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Enhancing participant preparedness in advance | x | x | x | | x | x | | | | | | | | x |
| Improving consistent and complex information sharing | | x | x | | x | | | | | | | | | |
| Enhancing access, recruitment and diversity | x | x | x | | x | x | | | | | | | | |
| Enhancing autonomy for vulnerable/specialized participant groups | x | x | x | | x | x | | | | | | | | |
| Improving participants' understanding | | x | x | x | x | | | | | | | | | |
| Reducing participants' dropouts | | x | x | x | x | | | | | | | | | |
| Enhancing the ability for flexible communication channels | | | | | x | | | | | | | | | |
| Increasing the quality of consent data | | | | | | | | | x | x | x | x | x | |
| Improving compliance with the consent process | x | | x | x | | | x | x | x | x | x | x | x | |
| Improving tracking and insights into optional consents | | | | | | | | | x | x | x | x | x | |
| Improving oversight and real-time insights | x | | x | x | | | x | x | x | x | x | x | x | |
| Enabling integration with other systems | x | | | | x | | x | | | x | x | | | |
| Reducing on-site consent auditing and inspection activities | x | | | x | | | x | x | x | x | x | x | | |
| Reducing on-site consent monitoring activities | x | | | x | | | x | x | x | x | x | x | x | |
| Enhancing continuous improvement of consent content | | | x | x | | | | | | | | x | | |
| Supporting sites to have a more tailored discussion with the participant | | | x | x | | | | x | | | | x | | |
| Improving consent storage | | | | | | x | | | x | | | | | |
| Improving consent archival for sites | | | | | | x | | | x | | | | | |

Overview of **digital features with high impact** for each **eConsent benefit.**

# Digital Features vs Benefits – Some Examples

**Digital features** such as **educational content, comprehension content and communication channels** have **a high impact on benefits directly impacting participants**

| | Pre-Consent Acknowledgment | Educational content | Comprehension Content | Comprehension Confi | Communicat | Cons | Iden | Bu | Sign | Pape | Con | Met | Bus | Noti |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Enhancing participant preparedness in advance | x | x | x | | x | x | | | | | | | | x |
| Improving consistent and complex information sharing | | x | x | | x | | | | | | | | | |
| Enhancing access, recruitment and diversity | x | x | x | | x | x | | | | | | | | |
| Enhancing autonomy for vulnerable/specialized participant groups | x | x | x | | x | x | | | | | | | | |
| Improving participants' understanding | | x | x | x | x | | | | | | | | | |
| Reducing participants' dropouts | | x | x | x | x | | | | | | | | | |
| Enhancing the ability for flexible communication channels | | | | | x | | | | | | | | | |
| Increasing the quality of consent data | | | | | | | | | x | x | x | x | x | |
| Improving compliance with the consent process | x | | x | x | | | x | x | x | x | x | x | x | |
| Improving tracking and insights into optional consents | | | | | | | | | x | x | x | x | x | |
| Improving oversight and real-time insights | x | | x | x | | | x | x | x | x | x | x | x | |
| Enabling integration with other systems | x | | | | x | | x | | | x | x | | | |
| Reducing on-site consent auditing and inspection activities | x | | | x | | | x | x | x | x | x | x | | |
| Reducing on-site consent monitoring activities | x | | | x | | | x | x | x | x | x | x | x | |
| Enhancing continuous improvement of consent content | | | x | x | | | | | | | | x | | |
| Supporting sites to have a more tailored discussion with the participant | | | x | x | | | | x | | | | x | | |
| Improving consent storage | | | | | | x | | | x | | | | | |
| Improving consent archival for sites | | | | | | x | | | x | | | | | |

# Digital Features vs Benefits – Some Examples

**Digital features** such **as confirmation of participation, signed consent upload, paper consent tracking** have a **high impact on benefits specifically for the sponsor**

| | nsent Acknowledgment | tional content | omprehension Content | Comprehension Confirmation | Communication channels | Consent Document Copy | Identity/authentication | Documentation/Log | Signed Consent Upload | Paper Consent Tracking | Confirmation of Participation | Metadata Insights and Metrics | Business Intelligence | Notifications |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Enhancing parti | | | | x | x | | | | | | | | | x |
| Improving cons | | | | x | | | | | | | | | | |
| Enhancing acce | | | | x | x | | | | | | | | | |
| Enhancing auto | | | | x | x | | | | | | | | | |
| Improving parti | | | x | x | | | | | | | | | | |
| Reducing participants' dropouts | | x | x | x | | | | | | | | | | |
| Enhancing the ability for flexible communication channels | | | | | x | | | | | | | | | |
| Increasing the quality of consent data | | | | | | | | | x | x | x | x | x | |
| Improving compliance with the consent process | x | | x | x | | | x | x | x | x | x | x | x | |
| Improving tracking and insights into optional consents | | | | | | | | | x | x | x | x | x | |
| Improving oversight and real-time insights | x | | x | x | | | x | x | x | x | x | x | x | |
| Enabling integration with other systems | x | | | | x | | x | | | x | x | | | |
| Reducing on-site consent auditing and inspection activities | x | | | x | | | x | x | x | x | x | x | | |
| Reducing on-site consent monitoring activities | x | | | x | | | x | x | x | x | x | x | x | |
| Enhancing continuous improvement of consent content | | | x | x | | | | | | | | x | | |
| Supporting sites to have a more tailored discussion with the participant | | | x | x | | | | x | | | | x | | |
| Improving consent storage | | | | | | x | | | x | | | | | |
| Improving consent archival for sites | | | | | | x | | | x | | | | | |

Note – also other platform and operational aspects and how to mitigate eConsent challenges are covered in the framework

# Step 3 – Evaluate Your eConsent Objectives and Aspects Upfront with Selected Stakeholders

**Highly recommended** to **cross-check your assumed eConsent objectives and related aspects** for your study upfront with **some selected stakeholders**

## 6. STEP 3: EVALUATE WITH SELECTED STAKEHOLDERS THE TARGETED eCONSENT OBJECTIVES AND ASPECTS FOR YOUR STUDY

### 6.1. Introduction

The eConsent objective and aspects (platform, operational) have been defined for your study. eConsent platform vendor(s) that can best support your study have been contacted and you have a good view on how you want to deploy the different eConsent aspects in line with the vendor capabilities.

An upfront evaluation with selected stakeholders is highly recommended to confirm or cross-check your assumed eConsent objectives and related eConsent platform and operational aspects. This also allows you to further tailor and update your eConsent platform and o

### 6.2. eConsent Stakeholders' E

Using the targeted eConsent benefits have answered or cross-checked.

Since the goal of this upfront evalu recommended to have detailed and o aspects, and operational aspects to Preferably, include practical and tangil a correct understanding.

Internal sponsor departments (e.g. pa with developing the questions for par or provide the answers you are lookin

| Methodologies | Advantages | Disadvantages |
|---|---|---|
| Surveys (electronic, on paper) | Low resource need<br>Low time-investment<br>Potential for large audience | High risk of misunderstanding<br>Limited insight into feedback and rationale<br>Potential low response rate |
| Group Meetings (video call, face-to-face) | Detailed insight in feedback and rationale | High resource need<br>High time investment<br>Potential for vocal person intimidating others |
| Interviews (video call, face-to-face) | Detailed insight in feedback and rationale | Very high resource need<br>Very time intensive<br>Personal opinion of one person |

Different methodologies for sponsor to collect stakeholder's feedback

**Go/No Go eConsent Decision For Your Study**

# Step 4 – Define the eConsent Metrics and Measurements for Your Study and Stakeholders

| Key Performance Indicators | Description | How to measure? |
|---|---|---|
| Monitor Experience | Measuring impact of eConsent on monitoring activities | • Use surveys, group meetings, and interviews to<br>impact on informed consent review, platform u<br>• Develop additional reporting capabilities for pla<br>internal company reporting tools) to enable me<br>time spent by the monitor on site versus remot |
| Sponsor Experience | Measuring impact of eConsent on sponsor activities (not monitor) | • Use surveys, group meetings, and interviews to<br>management, regulatory, IT, privacy, procurem |
| Participant Experience | Measuring impact of eConsent on participant | • Use surveys, group meetings, and interviews to<br>eConsent (e.g. participant satisfaction).<br>• Identify metrics from eConsent platform, such<br>eConsent platform by participants, participant'<br>some insights. However, these need to be inter<br>assumptions). Comparison with paper-based m<br>available data. |
| Site Experience | Measuring impact of eConsent on site activities | • Use surveys, group meetings, and interviews to<br>site-participant relationship, site workload).<br>• eConsent platform metrics, such as site training<br>platform, site's helpdesk metrics (if applicable),<br>need to be interpreted with the necessary prec<br>paper-based methods may also be challenging |
| Inspection/Audit Findings | Measuring impact of eConsent on consent inspection/audit findings | • Specify number and classification of inspection/audit findings related to eConsent activities.<br>• Verify number of CAPA (Corrective and Preventive Actions), including the time from setup to closure and any additional required actions. |
| Consent Protocol Deviations | Measuring impact of eConsent on consent protocol deviations | • Analyze number of eConsent protocol deviations, if available. Informed consent is often a specific category of protocol deviations (e.g. missing date, issue with signature, wrong version). |
| Recruitment Rate | Measuring impact of eConsent on recruitment numbers | • Use surveys, group meetings, and interviews to collect data on the impact of recruitment and/or increased access from participants and sites.<br>• Using overall participants' recruitment data can be difficult/challenging due to the multi-factor/complex nature of the recruitment process. |
| Dropout Rate | Measuring impact of eConsent on drop out numbers | • Use surveys, group meetings, and interviews to collect impact on dropout rate from participants.<br>• Using overall participants' drop data can be difficult/challenging as dropout is a multi- |

- Monitor Experience
- Sponsor Experience
- Participant Experience
- Site Experience
- Inspection/Audit Findings
- Consent Protocol Deviations
- Recruitment Rate
- Dropout Rate
- Investments/Savings

- **9 Key Performance Indicators** (KPIs) were identified with **detailed qualitative and quantitative measurements** described in the framework.
- **Most measurements are qualitative** since the **data reporting capabilities** related to consent activities are **currently limited or fragmented** and require **careful understanding and interpretations**

# Step 5 – Define the eConsent Analysis and Reporting Approach

## 8.2. eConsent Analysis and Reporting Approach

There are different approaches on how to analyze the impact of eConsent digital features and other eConsent platform aspects and operational aspects for your study. The 2 most common approaches, including their advantages and disadvantages, are shown in Figure 9.

| eConsent Study Implementation Approach | eConsent Analysis Approach | Advantages | Disadvantages |
|---|---|---|---|
| **All participants/sites of the study are offered eConsent** | *Related to Participants'/Sites' Experience KPIs*<br>• Participant/site e<br>questioning the i<br>aspects versus th<br>format.<br>• The same partici<br>formats: e.g. init<br>reconsent witho<br>• For participants/<br>eConsent, the ex<br>collected.<br>*Related to moni*<br>*other KPIs*<br>• Monitor/sponso<br>questioning the impact of various eConsent aspects compared with the traditional consent process.<br>• Other KPIs might be evaluated by comparing them with historical data of other comparable studies: e.g. inspection/audit findings related to consent, dropout rates. | Perspective of All | Less simple comparison |
| **Selected group of participants/sites of the study are offered eConsent** | *Related to Participants'/Sites' Experience KPIs*<br>• Participant/site experience is evaluated in line with the consenting format received.<br>• For evaluating impact on traditional paper consent process, equivalent paper documents (e.g. quiz) might need to be provided or questions specifically tailored (e.g. would upfront provision of information be helpful).<br>*Related to monitor/sponsor experience KPIs and other KPIs* | More straightforward comparison methodology | • Perspective of a selected group of study participants and sites<br>• Evaluation of traditional consent approach might be more difficult for certain aspects<br>• Potential bias within the study on how participants are informed |

**All participants/sites** of the study are offered eConsent

**Selected group of participants/sites** of the study are offered eConsent

- Different approaches to analyze **your KPIs** with their **advantages and disadvantages**
- Additional considerations are also listed, e.g. **the timing of assessment might vary depending on the KPI**

# eConsent Fit-for-Purpose Study Framework - Key Takeways

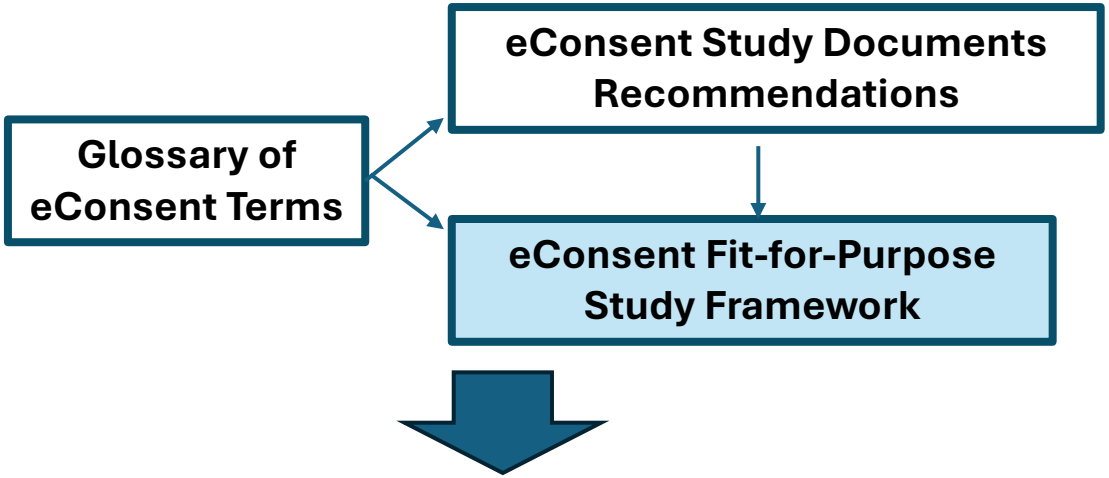
- There is **NO one-size fits-all eConsent**. Each Study, each indication, each site, each participant might have different needs
- **Define your eConsent objectives for your study upfront**, and **select the best matching platform and operational aspects** to reach your goal
- **Don’t assume, do an upfront check with your stakeholders**
- **Generation of effective and comparable eConsent study data**, and **sharing of outcomes**, is **critical** for eConsent adoption

eConsent Fit-for-Purpose Study Framework

3

# The Path to eConsent Success is In Your Hands

# A Whole Suite of eConsent Tools Available




**Let's work together to bring eConsent to the place it deserves!**

***Please scan the QR code to access all EFGCP eConsent resources or go to www.efgcp.eu!***

4

# Questions & Answers

# Thank You!

**EFGCP eConsent Initiative With the Support Of**

Roche IQVIA TECHNOLOGIES MEDIDATA

For questions & feedback on the tools: hilde.vanaken@efgcp.eu

A short webinar FU survey will be sent in the coming days!